UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,981	03/02/2007	Martin Leonard Ashdown	5517-18	8112

22442 7590 12/01/2009

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,981	ASHDOWN, MARTIN LEONARD	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-50,52-56,58,59 and 61-65* is/are pending in the application.

4a) Of the above claim(s) *48,52-56 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-47,49,50,58,59,61 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 45-50, 52-56, and 58, 59, and 61-65 are pending in the application.

2. In the prior action, the Final action mailed on September 3, 2009, claims 45-50, 52-56, and 58-65 were pending in the application; with claims 48, 52-56, and 63-65 withdrawn from consideration; and claims 45-47, 49, 50, and 58-62 under consideration and rejected.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 18, 2009 has been entered.

In the November 2009 submission, the Applicant amended claims 45, 46, and 63-65; and cancelled claim 60.

4. Claims 45-47, 49, 50, 58, 59, 61, and 62 are under consideration.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 45-47, 49, 50, 58, 59, 61, and 62 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods wherein the agent is an agent antagonistic to the production or activity of regulator cells (i.e. the agents of claim 60), does not reasonably provide enablement for the claimed methods wherein the agent is any agent suitable for the treatment of the disorder. In view of the amendment of the claims to incorporate the limitations of claim 60, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

6. **(Prior Rejection- Withdrawn)** Claims 45-47, 49-50, and 58-62 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 2003/068257 (WO'257- of record in the March 2007 IDS). In view of the amendments to the claims, the rejection is withdrawn in favor of the obviousness rejection below.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **(New Rejection)** Claims 45-47, 49-50, 58, 59, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/068257 (WO'257- of record in the March 2007 IDS) as previously applied further in view of Huber et al. (Cancer Res 40:3484-90). The claims have been described previously, except that they have been amended to require that the monitoring step of the claimed method involves the monitoring of the patients immune system for a period representing at least one cycle of the patient's immune system. The Applicant asserts that the teachings of WO '257 fail to teach such immune system cycling, or to suggest a method including a monitoring step for the purpose of understanding the dynamics of the immune system cycling (as required, for example, but amended step ii) of claim 45). Applicant's arguments are

found persuasive with respect to the teachings of the WO reference alone. Thus, the anticipation rejection over the reference has been withdrawn.

However, other teachings in the art indicate that those of ordinary skill in the art would have expected the presence of such immune system cycling. See e.g., Huber et al., abstract, and page 41 (each teaching the cycling of immune of the immune system between periods of cytotoxic and suppressor cell activity). In view of the knowledge of such cycling in the art, it would have been obvious to those of ordinary skill in the art from the teachings of the WO reference that monitoring for a sufficient period of time to determine the dynamics of the immune system cycling could be performed so as use such knowledge to aid in determining when to most advantageously administer agents inhibiting suppressor/regulator cell production or activity (e.g. to aid in the prediction of when the numbers/activity or suppressor cells targeted by the anti-suppressor cell agents is likely to occur).

Thus, while the teachings of the WO reference alone do not teach or suggest the claimed invention, the combined teachings of that reference with the knowledge of immune system cycling such as is indicated by the teachings of Huber would have rendered the claimed methods obvious to those of ordinary skill in the art.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. **(Prior Rejection- Restated as Necessitated by Amendment)** Claims 45-47, 49, 50, and 58-62were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 33-35, 37, 38, and 45-47 of copending Application No. 10/503794. The rejection is restated as a rejection of claims 45-47, 49-50, 58, 59, 61, and 62 over the indicated claims of copending Application 10/503794 in view of the teachings of Huber. The rejected claims have been amended as described above. While the copending claims are silent as to the monitoring for and analysis of the immune system cycling of the patient to be treated, the inclusion of such steps would have been obvious to those of ordinary skill in the art based on the indications in Huber that those of ordinary skill in the art would have known about such cycling, and the combined teachings of the Huber reference and the copending claims indicating that knowledge and understanding of the cycling in the patient would be useful in determining when an agent to suppress suppressor cell activity should be administered to optimize its effects in targeting the suppressor cells. The present claims therefore represent an obvious embodiment of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. **(Prior Rejection- Restated)** Claims 45-47, 49-50, and 58-62 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 10-13, and 15 of copending Application No. 12/333/369. It is noted that the rejection should have referred to claims 1-4, 6, 10-13, and 15 of copending Application 12/233,369, and not 12/333,369. The rejection is restated as a rejection of claims 45-47, 49-50, 58, 59, 61, and 62 over the indicated claims of copending Application 12/233,369 in view of the teachings of Huber. The presently rejected claims have been amended as described above. While the copending claims silent as to the monitoring for and analysis of the immune system cycling of the patient to be treated (e.g., steps i) and ii) of claim 45), the inclusion of such steps in the claimed methods would have been obvious to those of ordinary skill in the art based on the combined teachings of the copending claims and of Huber for the same reasons as indicated above in the obviousness rejection or in the non-statutory double patenting rejection based on the '794 application above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648